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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/421,213	10/20/1999	TIMOTHY J. O'BRIEN	D6064CIP	3804
27851	7590	02/26/2004	EXAMINER	
			HARRIS, ALANA M	
		ART UNIT		PAPER NUMBER
				1642

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/421,213	O'BRIEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 30 October 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 22-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 25-52 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 22-24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

**DETAILED ACTION**

1. After review and reconsideration the Finality of the instant case has been withdrawn (set forth in Paper number 26, mailed 05 November 2002). Prosecution in this application has been reopened and a Non-Final Office Action is set forth below.

2. Claims 1-52 are pending.

Claims 1-21 and 25-52, drawn to non-elected inventions are withdrawn from examination.

Claims 22-24 are examined on the merits.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 23 is vague and indefinite in the recitation "means to detect said antibody". This claim does not recite complete method steps. While it is clear from independent claim 22 that there is the detection of a TADG-15 protein the claims do not provide how the antibody is detected. It is not clear how the antibody-detecting step should be implemented. It is not clear if for instance, a reagent or apparatus used to

perform the specified function. Accordingly, the metes and the bounds of the claims cannot be determined.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Japanese document, J09149790-A (10 June 1997). A translation of Japanese document, J0914970-A has been provided by the Patent and Trademark Offices' Translations Branch and accompanies the said Japanese document and attached database sheet. J0914970-A discloses a serine protease of 241 amino acid residues the same as amino acid residues 615-673 and 675-855 of Applicants' SEQ ID NO: 2, a Tumor Antigen Derived Gene-15 (TADG-15), see attached database sheet; page 1 of translation, sections denoted as claim 1 and claim 2; and J0914970, pages 12 and 13, sequence 723. In section 0025 of the translation "...a specific antibody at the serine protease of this invention..." is disclosed. This antibody is the same as that claimed.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese document, J09149790-A (10 June 1997). The 102(b) rejection set forth above teaches an antibody that is specific for TADG-15 protein, SEQ ID NO: 2. Japanese document, J09149790-A does not teach a means to detect said antibody, or a kit for detecting TADG-15 comprising the antibody specific for TADG-15.

Applicants have argued in previous Remarks and in the Brief filed October 30, 2003 that “[t]he antibody generated according to the Examiner’s methodology would cross-react between Accession number W22987 and TADG-15 and would not be, therefore, specific for TADG-15”, see Brief, bridging paragraph of pages 9 and 10. Applicants further aver that “[i]n order to obtain TADG-15-specific antibody that would be useful in detecting TADG-15 protein specifically, one of ordinary skill in the art would generate an antibody against a sequence which is unique to TADG-15”, Brief, page 10, first full paragraph. These points of view and arguments have been carefully considered, but found unpersuasive.

The record reflects that the claims do not set forth that the antibody must bind to any particular or unique amino acids residues of the TADG-15 protein. The claims broadly encompass an antibody that is specific for TADG-15 protein, which consists of

855 amino acids. The Japanese document as seen in the attached database sheet denoted as Accession number W22987 reveals a 241 amino acid fragment that is a part of the TADG-15 protein. In particularity, the said fragment is commensurate with the serine protease domain of the TADG-15 protein. As provided in Applicants' application serine proteases are correlated with the aggressiveness of cancer and have been noted to be overexpressed in cancer and may contribute to malignant progression, see Description of the Related Art, pages 2 and 3. Clearly this section of the TADG-15 protein would be ideal in the generation of antibody contained in a detection kit.

Accordingly, although the claims recite a kit, no positive recitation of the kit ingredients/elements distinguishes the claim over the references. Therefore, the reference reads on the claimed kit. Further, it is a well-known convention in the art to place the recited elements in a kit for the advantages of convenience and economy, and methods of detection, diagnostics and therapies also were well known and available to the ordinarily skilled artisan. Thus, the claimed subject matter is considered obvious over the prior art, absent sufficient factual evidence to the contrary.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

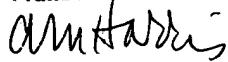
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne "Bonnie" Eyler, Ph.D. can be reached on (571)272-0871. The fax

phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER



Alana M. Harris, Ph.D.  
22 February 2004



YVONNE EYLER, PH.D  
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